IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
	)	C.A. No. 13-978-RGA
Plaintiffs,	)	C.A. No. 13-1272-RGA
v.	)	
WATSON LABORATORIES, INC.	)	
Defendant.	)	

DEFENDANT'S CORRECTED OPENING POST-TRIAL BRIEF

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Asserted claim 4 of the U.S. Patent No. 6,441,168 ("the '168 patent") is invalid under the on-sale bar provision of Section 102(b) of the Patent Act. Merck made a commercial offer to sell the claimed compound, and in fact sold the compound to Weider in a series of signed communications in September 1998, which is more than one year before the application date of the '168 patent. Merck made the offer in a September 9, 1998 fax to Weider, specifying all material terms of the sale, including quantity, price, payment terms, and delivery. Further, Merck expressly instructed Weider how to effectuate the sale. Weider accepted the offer in writing as well as by placing an order, and followed Merck's proffered instructions.

Contrary to Plaintiffs' suggestion, Section 5.2 of a confidentiality agreement between Merck and Weider in connection with a failed joint venture cannot negate this commercial reality. The parties' conduct reflected their mutual understanding that the terms of Section 5.2 did not prevent a sale from occurring, either because Section 5.2 did not apply to the stand-alone sale or because the signed exchanged documents satisfied the requirements of Section 5.2. In any event, as a matter of law, Merck waived any right to specific enforcement of Section 5.2 by proposing and inviting Weider to proceed with the sale in a manner that Merck claims to have known did not comply with Section 5.2.

The Court also should hold Claim 4 of the '168 patent invalid: (1) as anticipated by the Vecchi patent under Section 102(a); (2) as obvious in light of the Vecchi patent and prior art under Section 103; and (3) for lack of written description under Section 112.

I. THE ASSERTED CLAIM IS INVALID UNDER THE ON-SALE BAR.

A. Evidence of the Offer and Sale

In late 1997, Merck sought a strategic partner to develop and introduce products containing new Merck ingredients into the fast-growing American market for dietary

supplements. (T714:3-18.)[1] To that end, Dr. Herwig Buchholz, a business development manager at Merck, met with Dr. Luke Bucci, the Vice President of Research for an American dietary supplement company called Weider Nutrition International ("Weider"). (T171:6-11.)

Shortly after the meeting, Dr. Buchholz asked Weider to execute a Confidential Disclosure Agreement ("CDA") to allow the parties to pursue what Dr. Buchholz described as a "strategic relationship," in which Weider and Merck would jointly develop new dietary supplement products that Weider would have exclusive rights to market in the United States. (T720:16-721:19, T92:20-93:8; DTX 63.) They contemplated a multi-year joint venture or collaboration to develop and market products with new ingredients, including the compound of Claim 4 – that is, "crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid with 2 theta values of 6.5, 13.3, 16.8 and 20.1 (Type I)," hereinafter reffered to as "MTHF." (T183:13-185:8; DTX 39; DTX 72 at 6.) Through the Spring and Summer of 1998, Dr. Buchholz and Dr. Bucci had frequent communications and numerous meetings, as the companies worked toward the strategic partnership. MTHF was to be the first Merck ingredient jointly developed and exclusively marketed by Weider. (T719:16-720:15; DTX 38 at 3.)

In late August 1998, however, Weider notified Merck that it no longer sought an exclusive strategic partnership with respect to MTHF. (DTX 80T at 1.) After Weider and Merck gave up seeking an exclusive strategic alliance for MTHF, Weider asked if it could do a stand-alone purchase of MTHF to develop its own products, with no exclusivity, mandatory marketing expenditures, or any other commitments required. (*Id.* at 1-2) Communications regarding the stand-alone purchase were handled by Dr. Roland Martin, who was responsible for Merck sales and marketing of nutritional materials, and members of Weider's marketing and purchasing

[1] Defendant's Opening Brief contained citations to the non-final trial transcript. As the final transcripts were subsequently released, the Defendant submits this Corrected Opening Brief, which only updates the transcript citations to correspond to the final transcript.

departments. (T84:4-10.) In the meantime, Dr. Bucci and Dr. Buchholz continued their discussions for a potential exclusive strategic partnership in the U.S. market with respect to other materials. (DTX 83; DTX 52.)

In a late August 1998 phone call with Weider, Dr. Martin discussed an order for 2 kilograms of MTHF, at $25,000 per kg, FOB delivered.[2] (DTX 80T; PTX 76.) By fax of September 2, 1998, Weider's Vice President of Marketing, James Hines, followed up on the call. He confirmed the amount of 2 kilograms, and asked for confirmation of price and payment terms. He wrote that Weider would like to do "the simplest thing for both companies" to complete the sale. (DTX 79.)

In an internal Merck memo dated September 4, 1998, Dr. Martin reported on the call, including the amount, price and delivery of MTHF. He acknowledged that there was no formal supply agreement in place between Merck and Weider, and that "the conclusion of such an agreement is no longer planned at this time." (PTX 76 at 2.) He also knew that no joint venture or strategic partnership agreement had been executed or was even expected. Nevertheless, Weider's requested $50,000 sale would have been the first sale of MTHF by Merck anywhere in the world, after years in development at Merck. (T112:7-14.) In Dr. Martin's words, the amount (enough for more than 62 million doses) was "huge" and the amount of money ($50,000) at that time was a "huge amount of money." (T110:11-22; DTX 46; T199:19-200:10.)

Merck decided to proceed with the sale without a supply or strategic partnership agreement. Dr. Martin replied to Weider by fax on September 9, 1998: "[W]e would like to handle your purchase of [MTHF] very simple. Therefore, please send the order to my attention

[2] Plaintiffs take issue with Watson's certified translation of Dr. Martin's description of the call as "the granting of an order and delivery." (DTX 80T at 1.) While Watson maintains that its certified translation is accurate, resolution of the linguistic dispute would not seem to matter, since Watson does not contend that Merck made an offer of sale during the phone call.

and I will arrange everything." (DTX 133.) He then confirmed the price, shipment terms, and payment terms: "The price is 25,000 US$ per kg 5-MTHF free delivered to your R&D center in the U.S. Payment terms are 60 days net." Further, he indicated they could make an "immediate[] delivery" of even more than the requested 2 kilograms, and that "[a]fter receiving your order you will get the official confirmation of the order." (DTX 133.) Finally, Dr. Martin referred all discussions of any new product joint development to Dr. Buchholz. (*Id.*)

On September 16, 1998, Weider's purchasing manager, Gary Jepson, responded to the September 9 fax. He accepted Dr. Martin's terms and invitation to submit the order, and made out a purchase order: "We will order 2 KG of the material against PO# 29337 for delivery to: Weider Nutrition Group, 2002 South, 5070 West, Salt Lake City, UT 84104. Please reference the PO number on all paperwork and be sure to include a packing list with the shipment." (DTX 26.)

On September 25, 1998, Dr. Martin provided Mr. Jepson with instructions to further expedite delivery. He wrote that the "easiest and quickest way to deliver" the MTHF was to send the order directly to Merck-Eprova. (DTX 27 at 1.) In this fax, Dr. Martin confirmed that the product to be sold was MTHF, Lot number ESF-118. (DTX 27 at 3.) Plaintiffs have stipulated that Lot ESF118 is the MTHF of Claim 4, and that the PXRD data of Example 1 in the patent (which contains all of the 2-theta values recited in Claim 4) is from Lot ESF-118. (DTX 17.) Accordingly, it is undisputed that the claimed invention was ready for patenting at the time of these communications. (*See* T864:12-23.)

On September 28, 1998, Mr. Jepson acknowledged receipt, and confirmed that he would send the order directly to Eprova. (DTX 82.) Merck subsequently confirmed placement of the order on October 8, 1998. (DTX 83.) According to Dr. Bucci, Weider thereafter was expecting delivery of the 2 kilograms in the fall of 1998, based on its order. (T226:3-7.) With no delivery

by mid-November, Weider became concerned enough to put the issue on the agenda for a December meeting: "We need to track our order and determine delivery date." (DTX 51.)

In the meantime, however, Merck had been pursuing a much more lucrative and exclusive U.S. deal for MTHF with one of Weider's competitors, Whitehall Robins. As Dr. Martin reported, "Whitehall Robins (AHP) was considered the ideal partner with its very successful multivitamin preparation Centrum." (DTX 229T at 2.)

Whitehall Robins made clear that it would require between 6 months and two years of exclusive rights to MTHF in the United States and Canada, in exchange for its commitment to Merck. (DTX 84 at 2.) And, on November 4, 1998, Dr. Martin sent Whitehall Robins a proposal offering the exclusive right to sell MTHF-containing products in the United States. The proposal indicated that Whitehall would purchase 3,000 to 5,000 kilograms of MTHF. (DTX 273.) For Merck to compromise that exclusivity by delivering more than 62 million doses of MTHF to Weider in the United States would have been at least problematic, if not prohibitive.

When Weider and Merck met on December 14, 1998, Weider raised the fact that it had not received delivery of the 2 kilograms. (T749:15-21.) According to Merck's minutes of the meeting, Merck responded it "[would] try and locate the order." (DTX 134 at 2.) Thus, during the time when Merck was pursuing Whitehall Robins, Merck changed from confirming Weider's order on October 8, 1998, to suggesting on December 14, 1998 that the order might be lost or perhaps was never received, or would take months to find. (T766:17-767:14.)

Unaware of Merck's Whitehall Robins proposal, Weider was planning to proceed with its MTHF upon delivery. Further, Merck knew that Weider was going forward. Merck minutes of the December meeting reflect that Weider had decided first to launch a MTHF stand-alone

product, in order to avoid a pending patent application thought to cover certain combinations of MTHF with other substances. (DTX 134 at 1; T751:21-753:17.)

In early January 1999, Weider management reconsidered its plan, and decided to cancel the order. By email of January 9, 1999, Dr. Bucci wrote Merck that management had made the "decision to cancel our existing order." (DTX 88.) Merck responded: "We are of course sorry about your decision, but we still feel that there is plenty of opportunity for our companies to work together." (DTX 89.)

Thereafter, Dr. Bucci and Dr. Buchholz continued to explore potential strategic partnerships with joint development and marketing of new products. However, nothing ever came of those discussions, and no strategic partnership was ever formed. (T208:6-15.)

B. The Asserted Claim Is Invalid Under Section 102(b) Because the Claimed Invention Was the Subject of Both a Commercial Sale and Offer of Sale More Than One Year Before the '168 Patent Application Was Filed.

Under Section 102(b) of the Patent Act, a claimed invention is invalid if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C § 102(b). The on-sale bar applies when two conditions are satisfied before the critical date: (1) the claimed invention must be the subject of a commercial sale or offer for sale and (2) the invention must be ready for patenting at the time.[3] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); *Hamilton Beach Brands, Inc. v. Sunbeam Prods.*, 726 F.3d 1370, 1374 (Fed. Cir. 2013). Once a defendant demonstrates a *prima facie* case for invalidity based on the on-sale bar, the burden shifts to the patent holder to "come forward with convincing evidence to counter that showing." *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971

[3] As explained above, plaintiffs do not dispute that the invention was ready for patenting in September 1998. (T864:12-865:6.)

(Fed. Cir. 1984); *Leader Techs., Inc. v. Facebook, Inc.*, 770 F. Supp. 2d 686, 712 (D. Del. 2011), *aff'd*, 678 F.3d 1300 (Fed. Cir. 2012).

As demonstrated below, the documents and Dr. Bucci's uncontradicted testimony show that Weider was expecting delivery of the 2 kilograms of MTHF from lot ESF-118. This evidence presents a strong *prima facie* case of invalidity based on a commercial sale, as well as a commercial offer of sale. The commercial sale occurred when Weider accepted Merck's terms in Dr. Martin's fax of September 9, 1998. But even if that were not a "sale" under Section 102(b), Dr. Martin's fax was a commercial offer of sale. Indeed, it was the archetypical detailed and customer-specific offer of sale repeatedly held by the Federal Circuit to be invalidating under Section 102(b).

Plaintiffs have failed to produce any "convincing evidence to counter" Watson's showing. They rely primarily on (1) a strained interpretation of Section 5.2 of the CDA to argue that there could be no sale or offer of sale as a matter of law because Merck was never legally bound to sell the MTHF, and (2) the uncorroborated *post hoc* testimony of Dr. Buchholz as to undisclosed alleged conditions of the sale. Neither constitutes "convincing" evidence that the documents were anything other than what they appear on their faces to be.

1. The Claimed Invention Was the Subject of a Commercial Sale by Merck to Weider in September 1998.

"A 'sale' under [the on-sale] bar occurs when the parties offer or agree to reach 'a contract . . . to give and pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.'" *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001) (quoting *Zacharin v. United States*, 213 F.3d 1366, 1370 (Fed. Cir. 2000)); *In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 481 F. Supp. 2d 1029, 1052 (N.D. Cal. 2007), *aff'd*, 536 F.3d 1343 (Fed. Cir. 2008).

A sale within this meaning of the on-sale bar occurred with Weider's September 16, 1998 written acceptance of Merck's terms in the September 9, 1998 fax. (DTX 133; DTX 26.) Dr. Martin had set forth all material terms of the purchase, including product, quantity, price, delivery and payment terms. (DTX 133.) Weider accepted and promised to pay for the MTHF by its email of September 16, 1998, when Mr. Jepson wrote: "I have been given a copy of your fax, dated 9-09-98 covering the price and terms. We will order 2 KG of the material against PO# 29337 for delivery to" the Weider facility proposed in Dr. Martin's fax. (DTX 26.) The September 25 fax proves that the subject matter of the offer was lot ESF-118, which is admittedly the claimed MTHF.

Plainly, at that time Merck and Weider had either reached or "agree[d] to reach 'a contract … to give and pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.'" *Special Devices*, 270 F.3d at 1355. If there were any doubt as to the latest possible precise date of the sale, it can also be said to have occurred with Weider's September 28, 1998 email promise to follow the expediting procedure provided in Dr. Martin's fax of September 25, 1998. And, finally, there plainly was a sale by the time Weider actually placed its order, confirmed by Merck on October 8, 1998. The fact that Weider subsequently canceled its order in January 1999 does not undo the fact of the sale back in September 1998.

2. Prior to the Sale, the Claimed Invention Had Been the Subject of a Commercial Offer of Sale by Merck to Weider.

It is well-settled under Section 102(b) that the offer of sale need not be accepted in order for the on-sale bar to apply. *See, e.g.*, *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001). The offer itself is invalidating so long as it is "sufficiently definite that another party could make a binding contract by simple acceptance." *Hamilton Beach*, 726 F.3d at 1374-

75 (quoting *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008)). "[T]he question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood." *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001); *Pfaff*, 525 U.S. at 67.

For the meaning of "commercial offer of sale" under Section 102(b), the Federal Circuit looks to a variety of sources, including the Uniform Commercial Code, the Restatement (Second) of Contracts, *Corbin on Contracts*, and the common law. *See, e.g.*, *Grp. One*, 254 F.3d at 1047-48 (citing all three sources with approval). The Federal Circuit, however, has not placed any one source above all others, and has declined to "offer rules or even binding guidance" for determining what is and is not an "offer for sale." *Id.* at 1048.

Most of these sources overlap in describing an offer as "the manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it." *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (quoting *Restatement (Second) of Contracts* § 24 (1981)). Thus, the Federal Circuit has held: "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under §102(b)." *Grp. One*, 254 F.3d at 1048.

To determine whether "a communication or series of communications rises to the level of a commercial offer for sale" requires consideration of both the language of the communications, as well as the circumstances surrounding the making of the alleged offer. *Id.* at 1047-48; *Leader Techs.*, 770 F. Supp. 2d at 723; *Honeywell Int'l Inc. v. Nikon Corp.*, 672 F. Supp. 2d 638, 642-43 (D. Del. 2009), *aff'd sub nom. Honeywell Int'l, Inc. v. Nokia Corp.*, 400 F. App'x 557 (Fed. Cir.

2010). The relevant circumstances of an alleged commercial offer of sale are: "[1] the context of any prior communications or course of dealing between the parties; [2] whether the communication was private or made to the general public; [3] whether the communication comes in reply to a specific request for an offer; and [4] whether the communication contains detailed terms." *Leader Techs.*, 770 F. Supp. 2d at 723-24; *Honeywell*, 672 F. Supp. 2d at 643; *See, e.g.*, *Fisher-Price, Inc. v. Safety First, Inc.*, 109 F. App'x 387, 392 (Fed. Cir. 2004) (citing 1 *Corbin on Contracts* § 2.2 and *Restatement (Second) of Contracts* § 26, cmt. c (1981)).

The language and circumstances surrounding Dr. Martin's September 9, 1998 fax establish that it was a commercial offer of sale of the claimed MTHF, as a matter of law. Dr. Martin's language was that of commitment to immediately deliver the MTHF upon Weider's assent to the terms. He did not qualify the offer in any way. In fact, he expressly invited Weider to send the order to this attention and promised Weider that he would "arrange everything." (DTX 133.)

The parties' prior communications and meetings with respect to MTHF had been extensive. Merck's offer was made privately, only to Weider, and not the general public. And, Dr. Martin's fax came in reply to a specific request for an offer. Each of these facts weighs in favor of an offer.[4]

Finally, Dr. Martin's fax was detailed with respect both to the necessary documentation for the sale, and the material terms. Dr. Martin assured Weider that Merck also desired to handle the sale as simply as possible: "[W]e would like to handle your purchase of [MTHF] very simple. Therefore please send the order to my attention and I will arrange everything." (DTX

[4] *See, e.g., Rich Prods. Corp. v. Kemutec, Inc.*, 66 F. Supp. 2d 937, 956-957 (E.D. Wis. 1999), *aff'd*, 241 F.3d 915 (7th Cir. 2001); *RBC Aircraft Prods., Inc. v. Precise Machining & Mfg.*, No. 3:10-cv-878 (SRU), 2014 WL 2219193, at *17 (D. Conn. May 29, 2014); *Orbis Corp. v. Rehrig Pacific Co.*, 970 F. Supp. 2d 875, 881 (E.D. Wisc. 2013), *appeal dismissed*, (Dec. 11, 2013).

133.) The September 9, 1998 fax contained all the material terms that courts find to be sufficient for commercial offers for sale: (1) a description of the product to be sold (MTHF); (2) the quantity of the goods (2 kg); (3) the price of the goods ($25,000 per kg); (4) delivery information ("free delivered to your R&D center in the U.S."); and (5) payment terms ("Payment terms are 60 days net"). *See, e.g.*, *Rich Prods.*, 66 F. Supp. 2d at 957; *Orbis Corp.*, 970 F. Supp. 2d at 881-82; *RBC Aircraft*, 2014 WL 2219193 at *17.

Watson is not aware of any case in which price, quantity, delivery, and payment terms were specified, but the court found no offer of sale due to a CDA or some alleged unwritten conditions for delivery. Indeed, in the context of Section 271(a) of the Patent Act (which provides that an "offer to sell" patented inventions in the U.S. is an act of infringement), the Federal Circuit has held that less-detailed written quotes constitute "offers to sell," even though the quotes declared on their faces that they were not offers. *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1379-80 (Fed. Cir. 1998). The Federal Circuit held that to treat these less-detailed quotes "as anything other than offers to sell would be to exalt form over substance." *Id.*; *Lucent Techs., Inc. v. Netbridge Networks Corp.*, 168 F. Supp. 2d 181, 227-28 (D. Del. 2001).[5]

Here, the language of the offer and its circumstances manifest an objective intent to be bound by the assent. Weider was justified in understanding that its assent to the bargain in Dr. Martin's September 9, 1998 fax was invited and would conclude it. *See Linear Tech.*, 275 F.3d at 1050 (quoting *Restatement (Second) of Contracts* § 24 (1981)). Merck's communications about the order in early September, 1998, considered alongside the September 9, 1998 fax, are

[5] The Federal Circuit has made clear that the meaning of "offer to sell" under Section 271(a) is the same as that for "offer of sale" in the on-sale bar provision of Section 102(b). *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1254 (Fed. Cir. 2000) ("[a]n offer for sale, whether made before or after a patent is applied for, or after it is granted, requires no more than a commercial offer for sale.") Accordingly, the substance-over-form approach of *3D Systems* applies to the "offer to sell" in Section 271(a) is equally applicable to determining the existence of an "offer of sale" under on-sale bar provision of Section 102(b).

objective contemporaneous evidence of Dr. Martin's intent that Weider's acceptance would create a contract of sale.

3. Neither Plaintiffs' Construction of Section 5.2 of the CDA Nor Their Undisclosed Alleged Conditions of Sale Can Overcome the Clear and Convincing Contemporaneous Evidence of an Offer of Sale and a Sale of the Claimed MTHF.

Plaintiffs' response is that Dr. Martin simply did not mean what he wrote to Weider in the faxes of September 9th and September 25th, and that Dr. Buccholz did not mean what he wrote to Weider in his letter of October 10, 1998. Merck urges the Court to ignore what Merck wrote, said (according to meeting minutes) and did at the time, because Merck was merely "gladhanding" Weider in hopes of a future business relationship. (T852:10-12, 853:7-8.)

Watson is not aware of any court accepting "gladhanding" for future business as a basis to ignore the commercial reality of documents. To the contrary, the Federal Circuit in *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1370 (Fed. Cir. 2007), affirmed *summary judgment* where the patentee argued that a detailed letter-offer was "merely a ramp up to a business relationship." The court concluded that the patentee's "post hoc effort to say [that it] did not intend what is abundantly plain from the price, quantity, and delivery terms on the face of the June 7 letter does not raise a genuine issue of fact." *Id.* Like the patentee in *Cargill*, Plaintiffs point to evidence of a hoped-for, potential future business relationship. (T753:22-756:3, T757:14-758:2; DTX 83.) As the Federal Circuit held, however, "[E]xpressing a desire to do business in the future does not negate the commercial character of the transaction then under discussion." *Cargill*, 476 F.3d at 1370.

a. Section 5.2 of the CDA Does Not Rebut Watson's Evidence of an Offer and Sale of the Claimed MTHF.

Plaintiffs' primary "gladhanding" defense is based on Section 5.2 of the CDA signed to facilitate discussions of the intended exclusive joint strategic partnership. It provides: "Unless

and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction." (DTX 65 at 4.)

Plaintiffs implicitly construe the term "such definitive agreement" to exclude the purchase documentation that Dr. Martin provided and requested when he told Weider, "I will arrange everything." (DTX 133.) Merck also construes "transaction" to mean the stand-alone purchase of MTHF, rather than the strategic partnership or relationship between the two companies that Dr. Bucci and Dr. Buchholz intended to pursue in signing the CDA.

Plaintiffs then argue that because the documents provided and requested by Merck from Weider were not "such a definitive agreement," and because the stand-alone sale was a "transaction," there was no way that Merck could have been contractually bound by the alleged offer or sale of the MTHF – and thus there could be no offer as a matter of law. Plaintiffs insist that Merck knew this at the time, even though there is no such evidence in the documents.

In this way, Plaintiffs seek to argue around the purpose of the on-sale bar, which is "to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed." *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983); *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1163 (Fed. Cir. 2006); *Medicines Co. v. Hospira, Inc.*, C.A. No. 09-750-RGA, 2014 WL 1292802, at *11 (D. Del. Mar. 31, 2014). The documents unambiguously show that Merck was attempting to profit from the commercial use of MTHF.

The Court also should reject Plaintiffs' theory under general contract law and the contract law of the state of Utah.[6] *First*, Plaintiffs misconstrue the terms of the CDA. Properly construed,

[6] The CDA contains a choice of law provision specifying Utah law. (DTX 65 at 4.) The Federal Circuit has held that a commercial sale or offer of sale under Section 102(b) is

the term "transaction" does not encompass the stand-alone sale, but rather refers to the type of corporate strategic relationship or joint venture that the parties sought to pursue at the time. Further, for a stand-alone sale, the term "such a definitive agreement" properly construed would encompass the purchase documentation provided and requested by Merck, which contained all material terms. *Second*, even if Plaintiffs' construction of these terms were correct, and Merck knew that the offer of sale and even the sale could be voided by resort to Section 5.2, Merck waived its right to do so by inviting Weider to follow a process for the sale that did not strictly comply with Section 5.2.

i. Plaintiffs Improperly Construe Ambiguous Terms in the CDA, Which Are Properly Construed Not to Apply to The Stand-Alone Sale, or to Be Satisfied by the Purchase Documentation Provided and Requested by Merck.

As a matter of contract law, the terms "such definitive agreement" and "transaction" are ambiguous, which is to say capable of at least two reasonable interpretations. Neither is defined in the CDA.[7] The term "*such* definitive agreement" plainly refers to a specific "definitive agreement" described elsewhere. However, "definitive agreement" does not appear anywhere elsewhere in the CDA.

Courts look to extrinsic evidence to determine whether a term is ambiguous. *Watkins v. Ford*, 239 P.3d 526 (Utah Ct. App. 2010), *aff'd*, 304 P.3d 841, as amended, (Utah 2013); *Daines v. Vincent*, 190 P.3d 1269 (Utah 2008); *In re New Valley Corp.*, 89 F.3d 143, 150 (3d Cir. 1996)

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determined by general contract principles, rather than state law. *Pfaff*, 525 U.S. at 67. However, the Court need not determine which controls interpretation of the CDA because the two bodies of law do not appear to conflict.

[7] *See Memdata, LLC v. Intermountain Health Care*, No. 2:08-CV-190 TS, 2010 WL 1529275, at *3 (D. Utah Apr. 15, 2010) (term is facially ambiguous due to "no definition or guidance" in contract as to its meaning); *In re Steele*, 996 F.2d 311 at 6 (10th Cir. 1993) (unpublished) (facial ambiguity where "no indication in the agreement how 'or otherwise' language is to be interpreted").

(citing *Restatement (Second) of Contracts* § 223 cmt b (1981)); *see also* U.C.C. § 2-202(a). Moreover, evidence of the parties' subsequent conduct, prior to any dispute, is strong evidence of facial ambiguity. *Keybank Nat'l Ass'n v. Sys. W. Computer Res.*, 265 P.3d 107, 112 (Utah Ct. App. 2011); *In re New Valley Corp.*, 89 F.3d at 150; *Upland Indus. Corp. v. Pac. Gamble Robinson Co.*, 684 P.2d 638, 642 (Utah 1984) ("A construction given [to a contractual provision] by the acts and conduct of the parties with knowledge of its terms, before any controversy has arisen as to its meaning, is entitled to great weight, and will when reasonable, be adopted and enforced by the court.") (citations omitted); *McNeil Eng'g & Land Surveying v. Bennett*, 268 P.3d 854, 860 (Utah Ct. App. 2011); *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 509 (3d Cir. 2005).

The term "transaction" in the CDA may be properly construed to mean the kind of strategic partnership or joint venture that Merck and Weider contemplated at the time they signed the CDA. This is the construction most consistent with the rest of the CDA and the extrinsic evidence. For instance, Section 5.1 is devoted to defining the circumstances under which either party can go public about the potential transaction. (DTX 65 at 4.) Section 3 restricts the use of confidential information to "evaluating a possible transaction with the Disclosing Party." (*Id.* at 3.) This type of control over publicity and "evaluating" a transaction is more consistent with a corporate joint venture or undertaking, rather than a single stand-alone sale of material. Tellingly, there are no documents connecting the one-off purchase of MTHF in any way to the joint venture Merck and Weider had earlier contemplated.

The conduct of the parties here plainly reflected their mutual understanding either that Section 5.2 did not apply to the stand-alone sale (*i.e.*, it was not the contemplated "transaction"), or that the signed communications completing the sale (signed, exchanged faxes) satisfied the requirements of Section 5.2 as the parties both understood them. Merck was aware that there was

no joint venture agreement in place, and not even a supply agreement. Nevertheless, Merck assured Weider that it "will arrange everything" for the purchase, and provided instructions for obtaining immediate delivery. Dr. Bucci testified that Weider was expecting delivery of the MTHF. (T226:3-7.) There is no evidence that Weider had that expectation for any reason other than that it had accepted Dr. Martin's offer, had placed an order, and had received confirmation that the order had been placed. This conduct does not reflect that either side believed that what appeared to be an offer and a sale on the face of the documents actually was illusory.

Plaintiffs offer only speculation that Merck's claimed contrary understanding might only be reflected in unspecified privileged documents, withheld from production and the Court. (T836:17-837:8.) Plaintiffs similarly speculate that Weider's alleged belief to the contrary might have come from an unknown privileged communication at the time between a Weider employee named Zoller (whom Plaintiffs did not call as a witness) and Weider's lawyers. (T848:13-849:1; PTX 94.)[8] The rest of Plaintiffs' evidence is the improper legal opinion of Dr. Bucci as to whether the September 9, 1998 fax, which he had not seen before this case, and the September 25, 1998 fax, which he also had not seen before this case, complied with Section 5.2 of the CDA, which he also had never seen before this case. (T221:6-16, T221:23-223:3, T223:4-225:6.)

ii. Even if Plaintiffs' Construction Were Correct, Merck Waived its Right to Seek Enforcement of Section 5.2 by Proceeding With and Inviting Weider to Proceed With the Stand-Alone Purchase in a Manner Merck Knew Did Not Comply With Section 5.2.

Even if Merck had been of the view that Section 5.2 of the CDA meant that its detailed offer and instructions could not be binding, Merck waived its right to demand compliance with

[8] Plaintiffs claim that PTX94, a January 6, 1999 internal email chain at Weider, is "[t]he most important document in the case." (T845:24-846:2.) Yet Plaintiffs did not present testimony from any of the authors, or even any of the Merck employees whose alleged statements the authors purported to write about.

Section 5.2 by its own conduct. It is well-settled that a party cannot manifest an intent to forebear requiring strict compliance, and then, after the fact, demand that strict compliance for purposes of getting out of the contract. Such conduct constitutes a waiver, as well as a breach of the duty of good faith. *Lone Mountain Prod. Co. v. Natural Gas Pipeline Co. Am.*, 984 F.2d 1551, 1557 (10th Cir. 1992). "[W]aiver may be established by conduct inconsistent with claiming the waived right or any action or failure to act evincing an intent not to claim the right." *Evcco Leasing Corp. v. Ace Trucking Co.*, 828 F.2d 188, 195 (3d Cir. 1987); *In re Krueger*, 192 F.3d 733, 738 (7th Cir. 1999); *Innospec Fuel Specialties, LLC v. Isochem N. Am., LLC*, No. 10-1642, 2012 WL 3682988, at *4 (D.N.J. Aug. 24, 2012); *see also* U.C.C. § 2-209(4).

That is precisely what Merck did here, assuming, as Plaintiffs insist, that Merck knew Section 5.2 would apply to the stand-alone sale, and would be violated by the sales process and documentation that Merck itself provided to Weider. To whatever extent Merck once may have had a right to insist on compliance with Section 5.2 for the stand-alone sale, Merck waived that right by its promise "to arrange everything" and its instructions to Weider – especially when considered in light of more than a decade of silence until this litigation.

b. Plaintiffs' *Post Hoc* and Uncorroborated Testimony of Undisclosed Conditions of the Stand-Alone Sale Fail to Rebut Watson's Evidence of an Offer and Sale of the Claimed MTHF.

Plaintiffs' secondary defense is that that Merck never intended to deliver the 2 kgs of MTHF until numerous contingencies on the sale were removed. There is, however, no documentary evidence that the sale was conditional. Rather, Dr. Martin expressly promised to "arrange everything" for "immediate delivery" of the MTHF. (DTX 133.)

Nevertheless, Dr. Buchholz testified that toxicology testing, stability testing, and intellectual property were known within Merck as pre-conditions to delivery, and that these

issues were not resolved until long after December 1998. (T740:16-17, 745:4-746:5.) According to Plaintiffs, Dr. Buchholz told Weider all of this during meetings. However, none of the detailed meeting minutes cited by Dr. Buchholz contain any indication that delivery would be delayed pending resolution of any of these contingencies. (T751:3-20; DTX 134 at 1.)[9]

Against Dr. Buchholz's uncorroborated testimony, there remains Dr. Bucci's testimony that Weider was expecting delivery of the 2 kg in the fall – as well as Dr. Martin's September 9, 1998 promise of "immediate[]" delivery, and his September 25, 1998 instructions for the "quickest" delivery. (T226:3-7; DTX 133; DTX 27 at 1.) Plaintiffs would seem to say that Dr. Bucci was lying when he said he expected delivery, and that Dr. Martin was less than truthful in having promised immediate delivery. There is no evidence to support either contention.

For these reasons, the Court should hold claim 4 invalid under 35 U.S.C. § 102(b).

II. THE ASSERTED CLAIM IS ANTICIPATED BY THE '850 PATENT.

U.S. Patent No. 5,350,850 ("Vecchi") anticipates claim 4 of the '168 patent. Some of the elements are disclosed expressly, and at least one is disclosed inherently—but the evidence of anticipation is clear and convincing. Vecchi discloses a detailed synthetic and recrystallization method for obtaining a specific end product, the crystalline pentahydrate of MTHF. The Examiner acknowledged this during prosecution. After extensive screening for additional MTHF polymorphs and hydrates, the only known crystalline form of MTHF that could form a pentahydrate is "Type I." Finally, it is undisputed that the 2-theta values recited in claim 4 of the '168 patent are inherent properties of "Type I" MTHF.

[9] Dr. Martin testified by deposition that there were nine items that needed to be collected internally at Merck before the order could ship. He identified these in an internal memo dated September 4, 1998. (DTX 80T at 2.) All nine pieces of information were provided to Dr. Martin on September 21, 1998. (DTX 233T.)

No testing was needed to determine that Vecchi anticipates claim 4. But Dr. Rogers nevertheless confirmed that the recrystallization process taught in Vecchi yields "Type I" MTHF exhibiting the four 2-theta values recited in claim 4, even if the claimed compound had not been produced during the preceding synthesis – even though that routine synthesis was reported to produce some crystalline forms, possibly even MTHF. (T409:7-23.) That is, Dr. Rogers selected a starting material that was even less likely to produce the MTHF than the starting material for that step in the Vecchi patent. In this way, he proved that the recrystallization in boiling water actually formed MTHF.

A claim is invalid for anticipation if a single prior art reference discloses each claim limitation, either expressly or inherently. *Schering Corp v. Geneva Pharm.,* 339 F.3d 1373, 1377 (Fed. Cir 2003). A prior art reference inherently discloses a claim limitation if one of skill in the art, reading the reference, would "at once envisage" the claimed invention. *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). Inherent anticipation does not require the person of ordinary skill to have recognized the inherent feature at the time. *Id.* at 1377; *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002).

Although a prior art reference must be enabling to be anticipatory, issued patents cited during prosecution of the asserted patent are presumed to be enabling, and the party asserting validity bears the burden to prove otherwise by a preponderance of evidence. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324-26 (Fed. Cir. 2003); *Cubist Pharm., Inc. v. Hospira, Inc.*, C.A. No. 12-367, 2014 WL 6968046, at *13 (D. Del. Dec. 8, 2014). "Whether a prior art reference is enabling is a question of law based upon underlying factual findings." *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006).

A. The Vecchi Patent Inherently Anticipates Claim 4 Based on the Work and Product Disclosed in the Specification.

Claim 4 requires "a crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid with 2-theta values of 6.5, 13.3, 16.8 and 20.1 (Type I) said crystalline salt having a water of crystallization of at least one equivalent per equivalent of 5-methyltetrahydrofolic acid." (DTX 2 at col. 10:57-61.) Example 3 of Vecchi describes a single product (the "Vecchi product") that meets all limitations of claim 4 either expressly or inherently. (DTX 332 at col. 4:5-13.) No testing is required to reach this conclusion.

The Vecchi product is described by Vecchi as crystalline MTHF with a measured water content of "15.27%." (*Id*.) That water content translates to about five waters of crystallization, which is known as a "pentahydrate." Of the crystalline forms of MTHF known and discovered through Plaintiffs' own extensive investigations, *only* the Type I of claim 4 has been shown to exist as a pentahydrate. The water content of one of those forms is not reported, but the Vecchi product cannot be that form, because their water solubilities are too different. Thus, the Vecchi product can only be the Type I MTHF of claim 4. As a pentahydrate, the Vecchi product necessarily meets the limitation of having "at least one" water of crystallization. Finally, because 2-theta values are inherent properties of a crystalline form, the Vecchi product inherently and necessarily exhibits the four 2-theta values recited in claim 4.

1. Of the Crystalline Forms Disclosed in the '168 Patent and Plaintiff's Internal Documents, Only Type I Forms a Pentahydrate.

The '168 patent discloses four crystalline forms of MTHF (Types I-IV), and Plaintiffs' internal documents disclose a fifth. (DTX 2 at Figs. 1-4, cols. 2:4-9, 2:25-27, 4:29-35; T272:17-275:22.) The '168 patent states that Type I MTHF typically contains $\geq$ 3 waters, and reports Type I having a water content of 14.5% in Example 7 and 12.2% in Example 9. (T260:15-18, T261:14-24.) A water content of 14.5% is close to a pentahydrate. (T261:14-17.) None of the

other known forms even approach a water content corresponding to a pentahydrate. The '168 patent describes Type II as having two or less waters of crystallization, and reports Type II water content as 5%. (DTX 2 at Example 9; T260:19-21, T262:3-4.)

The '168 patent does not provide water content data for Type III, but Plaintiffs' internal documents report a 9.9% water content for Type III, which is about three waters of crystallization. (DTX 302 at 10; T274:22-277:3, T279:12-22.) For Type IV, the patent reports water content of 9.9% or 5.5% in Example 11. (T262:5-8.) Plaintiffs' internal documents do not report water content for the additional form disclosed in those documents. (DTX 302 at 10; T276:15-18.)

As Dr. Rogers explained, the '168 patent contains a typographical error stating that Types III and IV typically contain "$\leq$ 5" waters of crystallization. Consistent with the Swiss priority application and the actual data disclosed in the specification, the '168 patent should instead say that Types III and IV typically contain "$\leq$ 3" waters of crystallization. (Compare DTX 1 at 76:24-29 to DTX 2 at col. 2:12-19; *see also* T260:22-261:5, T264:12-21, T265:11-266:4, T274:22-277:3, T279:12-22.) Dr. Rogers' opinion on this matter is undisputed.

Indeed, there is no alternative interpretation or explanation for this discrepancy in the record. Dr. Myerson did not point to any data suggesting that Types III or IV actually can have greater than three waters of crystallization. Rather, when asked whether he agreed that only Type I can exist as a pentahydrate, Dr. Myerson evaded by citing back to the very language in the '168 patent that contradicts the Swiss priority application. (T634:10-13.) Dr. Myerson did not even mention the Swiss priority application or the actual water content data for Types III and IV reported in the patent. And when asked if there was any evidence that Type II could form a pentahydrate, Dr. Myerson simply noted that the patent does not affirmatively rule out that

possibility. (T634:24-635:8.) In a bid to cast doubt, Plaintiffs speculate that there *might* be some undiscovered crystalline form of MTHF capable of forming a pentahydrate, based on tales about other unrelated drugs. (T641:6-644:10.) Such speculation lacks probative value.

Plaintiffs themselves conducted and commissioned extensive studies for the express purpose of identifying other crystalline forms and hydrates of MTHF, but Plaintiffs *never* found a pentahydrate other than Type I. (T280:8-286:14; DTX 302 at 23-58 and 59-84.) Dr. Rogers reviewed those studies and concluded that it is "highly unlikely" that there is an undiscovered pentahydrate form of MTHF. (T286:4-14.) In the end, Dr. Myerson conceded that he is not aware of any other crystalline forms of MTHF, let alone another pentahydrate. (T681:17-19.)

2. Vecchi Discloses the Crystalline Pentahydrate MTHF, Which Could Be Only "Type I" MTHF.

To the extent that Plaintiffs claim Vecchi does not disclose the MTHF pentahydrate, they are contradicting not only Dr. Rogers, but also the U.S. Patent and Trademark Office ("P.T.O."). The Examiner during prosecution expressly found that the recited Vecchi product was crystalline, and that it was a pentahydrate of MTHF. (DTX 1 at 216-17; T264:22-265:8.) Dr. Rogers reached the same conclusion based on the same data. (T271:3-271:19, T288:20-295:4.)

Against Watson and the P.T.O., Plaintiffs again try to cast doubt through speculation. Dr. Myerson speculates that because Vecchi omits reference to the standard procedure of drying the product of Example 3 before measuring its water content, the 15.27% water content reported in Vecchi might include water in addition to waters of crystallization, and thus not reflect that the product obtained was a pentahydrate. (T640:12-641:5.) But Dr. Myerson admitted that drying before measuring water content is standard practice in the field. (T684:3-9.) Yet, Dr. Myerson points to no affirmative indication that Vecchi deviated from this standard practice. Instead, Dr. Myerson asks this Court to infer from silence that Vecchi deviated from standard practice

because Vecchi does not expressly describe that standard practice. Notably, Dr. Myerson himself drew precisely the opposite inference from similar silence in Merck documentation containing water measurements which Dr. Myerson wished to equate to waters of crystallization. (T682:1-24.)

Through a simple process of elimination, Dr. Rogers showed that the Vecchi product could only be Type I. As he explained, the Vecchi product could not be either Type III or Type IV, because it is a pentahydrate, and the '168 patent describes Types III and IV as typically having three or fewer waters of crystallization (typographical error notwithstanding). Indeed, the 15.27% water content of the Vecchi product is much higher than the 9.9% water content reported for Types III and IV (9.9%). (DTX 2 at col. 2:18-19 and Example 11; DTX 332 at col. 4:8; DTX 302 at 10; T301:2-302:16, T303:3-15.)

Dr. Rogers also explained that the Vecchi product could not be Type II because the '168 patent describes Type II as typically having no more than two waters of crystallization (DTX 2 at col. 2:16-18) and describes only Type II as occurring when there are two or fewer waters of crystallization. (DTX 2 at Example 9; T303:16-304:2.) The Vecchi product, by contrast, is a pentahydrate. (DTX 332 at col. 4:8; DTX 1 at 217; T303:16-304:2.)

Dr. Rogers further explained that the Vecchi product could not be the form identified in Plaintiffs' internal documents, because the Vecchi product was practically insoluble in water, whereas the type identified in the internal documents had "good" water solubility. (T302:17-303:2; DTX 332 at col. 4:9; DTX 302 at 10, 15.) Dr. Rogers then explained that the Vecchi product closely matched Type I, because both had very low water solubility and more than three waters of crystallization, approaching five. (T304:3-11.)

Finally, Dr. Rogers testified that the 2-theta values recited in claim 4 are inherent physical properties that would necessarily be exhibited by the substance disclosed in the '850 patent and now referred to as "Type I" MTHF. (T300:10-301:1, T304:12-304:22, T351:11-14.) This testimony is undisputed.

3. Dr. Myerson's Deviation From the Vecchi Method Cannot Overcome the Presumption that Vecchi Is Enabled.

Vecchi is presumptively enabled, and Plaintiffs bore the burden of overcoming that presumption by a preponderance of evidence. *Amgen Inc.*, 314 F.3d at 1324-26; *Cubist Pharm., Inc.*, 2014 WL 6968046 at *13. Plaintiffs failed to carry their burden. Dr. Rogers testified that one of skill in the art easily could have followed the process of Examples 1 and 3 in Vecchi to arrive at the Vecchi product, and that there is no basis to believe that such process was flawed in any way. (T294:10-295:4.) In response, Plaintiffs cite a single experiment that Dr. Myerson farmed out to a company called SSCI. (T644:11-647:14.) The experiment purports to show that if a person of skill tried to follow the synthetic steps of Examples 1 and 3 in Vecchi, that person would not obtain the Vecchi product. (T648:7-17.) As Dr. Rogers explained, however, the SSCI experiment deviated from the Vecchi process at a critical step—one that Vecchi itself described as "fundamental" to obtaining the final Vecchi product. (DTX 332 at 2:19-23.)[10]

SSCI's critical deviation explains why its experiment failed to obtain the Vecchi product. (T295:16-299:6, T371:2-372:13.) Dr. Myerson admitted that SSCI could have taken simple measures to try to compensate for its deviation, but chose not to. (T686:11-18.) Further, Dr. Myerson's lack of involvement in supervising SSCI's deviation renders his testimony on the

[10] Notably, Dr. Myerson did not suggest or approve this deviation by SSCI. Nor did he supervise, or even attend, the SSCI experiment while it was in progress. (T684:15-686:1, 686:19-687:11.) Plaintiffs chose not to produce the SSCI employees who made the decision to deviate, and the decision not to compensate or correct for the deviation.

subject entitled to little, if any weight. In short, because SSCI did not follow the Vecchi process, its failure to obtain the Vecchi product cannot overcome the presumption that Vecchi is enabled.

4. In Allowing Claim 4, the Examiner Misunderstood What Was Claimed in Relation to What Was Disclosed in Vecchi.

During prosecution, the Examiner determined that Vecchi disclosed crystalline pentahydrate MTHF. (DTX 1 at 216-17; T269:9-14.) The Examiner then allowed claim 4 to issue over Vecchi because Vecchi did not disclose the trihydrate. (DTX 1 at 188-89, 218; T269:15-270:5.) But claim 4 is not limited to the trihydrate. Rather, claim 4 refers to having "at least one" water of crystallization. "At least one" water of crystallization includes the pentahydrate. Thus, the examiner either understood claim 4 to be limited to the trihydrate (contrary to the plain language of the claim), or simply failed to apply Vecchi when allowing claim 4. Either way, the undisputed opinion of Dr. Rogers is that a person of skill in the art would conclude from the prosecution history that "a mistake had been made." (T269:15-270:5.)

B. Testing Confirms that the Recrystallization Method Taught in Vecchi Yields Crystalline Type I MTHF With the Four 2-Theta Values Recited in Claim 4.

No testing was required to demonstrate that Vecchi anticipates claim 4 calling for certain PXRD 2-theta values. The evidence is that such values are inherent. Nevertheless, Dr. Rogers went one step further to show that the Vecchi product really did exhibit the PXRD 2-theta values in claim 4. Dr. Rogers received MTHF from Dr. Marsden (Material 1), confirmed that it was amorphous using standard powder x-ray diffraction ("PXRD") methods, recrystallized Material 1 from boiling water as taught by Vecchi, and tested the resulting products (Material 2 and Material 3). (T351:15-352:6.) It is undisputed that Materials 2 and 3 were crystalline Type I MTHF exhibiting all four 2-theta values recited in claim 4. (T333:19-336:6, T338:17-339:8.)

Accepting that Materials 2 and 3 were the substance claimed in claim 4, Dr. Myerson asserts that Material 1 was "seeded" with Type I crystals and thus that Dr. Rogers' experiment

cannot prove that the Vecchi recrystallization yields the claimed invention. (T649:4-9.) Dr. Myerson did not conduct any testing of his own to support his assertion.

Instead, Dr. Myerson did a visual inspection of Dr. Rogers' PXRD diffractogram for Material 1. Based on that inspection, Dr. Myerson admits he could only identify one feature at about 6.5 2-theta. (T649:10-650:6.) The same was true after he conducted a subtraction. (T654:14-655:24.) Dr. Myerson relies on this single feature to conclude that Type I was present in Material 1. As an initial matter this approach is contrary to the '168 patent, which selected four peaks to claim Type I.

In any event, Dr. Rogers explained that the diffractogram feature for Material 1 at 6.5 2-theta does *not* indicate the presence of Type I crystalline MTHF in Material 1. Rather, Dr. Rogers explained that even amorphous materials yield some x-ray features, and the feature at 6.5 2-theta is "not uncommon for calcium salts of long molecules," which is why the *same feature* also appears in the diffractogram for *amorphous* MTHF in Figure 5 of the '168 patent. (DTX 2 at Fig. 5; T258:19-259:8, T316:22-318:17, T478:5-479:3.) Thus, the Material 1 diffractogram does not show that Type I was present in Material 1.[11]

Dr. Rogers compared the diffractograms for Material 1 and Type I of the '168 patent (Figure 1 of the '168 patent). (T318:18-328:11.) He testified that, based on this visual comparison, a person of ordinary skill would *not* believe that Material 1 contained any Type I crystalline material. (T328:2-11.) Tellingly, Dr. Myerson did not even testify about this comparison.

[11] Dr. Myerson offered only an *ipse dixit* to the contrary. (T669:24-670:22.) However, he did admit that multiple examples in the literature of *amorphous* calcium salts exhibited peaks at the low end of the spectrum, *even though they were amorphous*. (T671:4-679:15.) He further admitted failing to have conducted any experiments to determine the extent to which the calcium in Dr. Rogers' starting material accounted for a similar alleged peak. (T670:23-671:3.)

To mine for the other three Type I "peaks" in Dr. Rogers' XRPD data of Material 1, Dr. Myerson subtracted away data in a way known to create false, noise-induced peaks. (T339:12-340:6.) But even then, the resulting XRPD diffractogram did *not* match the PXRD of MTHF in Figure 1 of the patent – further evidence that Dr. Rogers' starting material was not "seeded" with Type I MTHF. (T341:10-20, T342:17-22.) Dr. Myerson then ran that data through a "peak search" computer program using parameters that were likely to find many false "peaks," even in admittedly amorphous material. (T340:6-10, T341:24-342:8, T342:23-347:6.)

Dr. Myerson ignored the multiple warnings from the user manual for his own software admonishing users not simply to accept the output of the automated peak search. (T347:7-350:18; DTX 357 at 304, 312, 558.) Dr. Rogers provided a detailed explanation of why Dr. Myerson's subtraction and peak search approach was deeply flawed, and lead to identification of many noise-induced peaks and even internally-inconsistent results that Dr. Myerson blithely interpreted as the same. (T342:23-347:6.) Dr. Myerson's only response to that critique was to generally agree that changing parameters can cause the peak search software to find fewer or more peaks. (T658:1-17.) At bottom, Dr. Myerson's efforts to mine the XRPD data for the recited peaks was biased, and thus should be discounted accordingly.

Accordingly, the Court should hold that claim 4 is anticipated by the presumptively-enabled Vecchi patent, and is therefore invalid under Section 102(a).

III. THE ASSERTED CLAIM IS OBVIOUS.

Obviousness is a question of law, based on underlying factual determinations including: "'the scope and content of the prior art'; 'differences between the prior art and claims at issue'; 'the level of ordinary skill in the pertinent art'; and '[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc.'" *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966); *Cadence Pharm. Inc. v. Exela Pharmscie Inc.*, 780 F.3d

1364, 1374 (Fed. Cir. 2015). "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Plaintiffs do not appear to challenge Dr. Rogers' testimony that crystalline calcium 5-methyl-(6S)-tetrahydrofolate was known and preferred (T377:12-379:3; DTX 347), that there was motivation within the industry to find and characterize crystalline forms (T379:7-383:4; DTX 334; DTX 325), that PXRD analysis was routine, and that PXRD peaks are inherent to a crystalline form. As Dr. Rogers explained, the person of ordinary skill would have a reasonable expectation of producing what is now known as the Type I MTHF based on the Vecchi patent alone. (T372:18-373:20.) Alternatively, the person of ordinary skill would have a reasonable expectation of doing so by combining the pentahydrate crystalline form of MTHF (Type I) as taught and disclosed in U.S. Patent No 5,006,655 with the recrystallization process of Vecchi, which Dr. Rogers' experiment validated. (T374:19-377:2, T383:5-385:3; DTX 345.)

Dr. Myerson's opinion of non-obviousness is based on his opinion that the prior art in general teaches away from heating organic materials, and the alleged impossibility of generally predicting a particular crystalline form of any material. (T661:13-664:11, T659:17-660:9.) As to the former, Dr. Myerson overlooks that the Vecchi patent is the closest prior art insofar as it deals specifically with 5-methy-(6S)-tetrahydrofolate molecule at issue. The Vecchi patent expressly teaches heating the compound (in boiling water) to make crystalline MTHF – the very antithesis of teaching away. (DTX 332 at col. 4:5-6.)

Similarly, Dr. Myerson's second point as to predictability and expectations is not specific to the type of molecule at issue here. Cross-examination revealed that there is a divide in the

scholarly community on the point (T688:18-690:16), that a person of ordinary skill would expect to find at least one crystalline form of a small organic pharmaceutical molecule (T686:4-14), and that at least half of the small pharmaceutical organic compounds were known by persons of ordinary skill to have polymorphs. (T688:7-16.) Thus, with respect to small pharmaceutical organic molecules such as the one at issue, a person of ordinary skill could have a reasonable expectation of being able to obtain the crystalline forms.

Accordingly, the Court should hold Claim 4 to be invalid as obvious over the Vecchi patent alone, or in combination with the '655 patent.

IV. THE PATENT LACKS THE REQUIRED WRITTEN DESCRIPTION FOR THE ASSERTED CLAIM.

Claim 4 of the '168 patent is invalid for failure to comply with Section 112 of the Patent Act, which "requires a patentee to provide a written description that allows a person of skill in the art to recognize that the patentee invented what is claimed." *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1341 (Fed. Cir. 2013). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor ha[d] possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted). It calls for the person of ordinary skill to make "an objective inquiry into the four corners of the specification." *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

The inventors chose to claim MTHF with "at least one equivalent per equivalent" or waters of crystallization. As Dr. Rogers explained, the specification does not disclose any information from which a person of ordinary skill would conclude that the inventors "possessed" MTHF (which is the type I crystal of the patent) with one water of crystallization, a

monohydrate. (T359:18-364:6.) Indeed, as Dr. Rogers observed, there is no written description of the claimed MTHF dihydrate either. (T804:1-6.)

Surprisingly, Dr. Myerson did not offer a specific opinion as to whether the specification conveyed to the person of ordinary skill possession by the inventors of a monohydrate of Type I MTHF. Instead, he opined that a person of ordinary skill would not conclude from the patent that it is scientifically impossible for the Type I MTHF to exist in monohydrate form. (T664:12-24.) He based that opinion on the patent's use of the word "typically," as non-prohibitive, with reference to the "≥3" range of waters in Type I MTHF. (DTX 2 at col. 2:15-18.)[12]

Accordingly, Plaintiffs' principle response is attorney argument that a person of ordinary skill would know that the claim's coverage of a monohydrate is impossible as a matter of science, and therefore would understand that the inventors neither claimed nor possessed the monohydrate of Type I MTHF. In this way, Plaintiffs are arguing for a claim construction that reads the monohydrate (and the dihydrate) out of the claim – that is, that changes "at least one" to "at least two" or "at least three." There are two problems with this. First, claim construction is behind us. Plaintiffs had their chance to make that argument at the appropriate time, but did not. It is waived. Second, it is well-settled that courts may not re-write unambiguous claims to save them from invalidity. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004). Plaintiffs did not contend that Claim 4 was in any way ambiguous.

Accordingly, the Court should hold that Claim 4 is invalid for failure to comply with the written description requirement of Section 112.

[12] Dr. Myerson offered only a conclusory opinion that the specification conveyed possession. (T665:14-19.) He did not provide any basis for that opinion, much less anything specific to the claimed monohydrate and dihydrate of MTHF. This is the same type of conclusory opinion that the Federal Circuit deems "insufficient as a matter of law" with respect to the written description requirement. *Ariad Pharm.*, 598 F.3d at 1357 & n.8.

Respectfully submitted,

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